APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,807	01/31/2005	Tsuyoshi Shiina	389.44708X00	6838

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EXAMINER
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ART UNIT	PAPER NUMBER
3768	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)
Office Action Summary	10/522,807	SHIINA ET AL.
	Examiner	Art Unit	
	LAWRENCE N. LARYEA	3768	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL**.   2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) <u>1-34</u> is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) <u>1-34</u> is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☒ The drawing(s) filed on <u>31 January 2010</u> is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All   b) ☐ Some * c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>05/06/2009 10/21/2008, 12/26/2007, 01/31/2005</u>

4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.

5) ☐ Notice of Informal Patent Application

6) ☐ Other: _____.

Claim Rejections - 35 USC § 112

1.   The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly
> claiming the subject matter which the applicant regards as his invention.

2.   Claims 2 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.   Regarding claim 2 and 21, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

At Claims 3, 8 lines 2, "set" should be change to --sets--

At Claims 3, 8 line 14, "include" should be change to --includes--

At Claims 5, 10, 12, 15, 18 line2, "detect" should be change to --detect--

At Claims 6, 16, line 2, "calculate" should be change to --calculate--

At Claim 19, line 2, "create" should be change to --creates--

At Claim 20, lines 1-2 recite the limitation "the displacement" and "the tissue"

There is insufficient antecedent basis for this limitation in the claim.

NOTE: The claims and specification are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with errors (see above rejections). Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the claims and specification. ***No new matter should be entered.***

Claim Rejections - 35 USC § 103

3.   The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set
> forth in section 102 of this title, if the differences between the subject matter sought to be patented and
> the prior art are such that the subject matter as a whole would have been obvious at the time the
> invention was made to a person having ordinary skill in the art to which said subject matter pertains.
> Patentability shall not be negatived by the manner in which the invention was made.

4.   Claims 1-4 and 20-23 are rejected under 35 U.S.C. 103(a) as being unpatentable

over **Alam et al (US Pub. 2002/0040187)** in view of **Shiina et al (Strain imaging using**

combined RF and envelope autocorrelation).

5.   **Alam et al** teach an ultrasonic diagnosis system comprising: an ultrasonic probe

(scanner) for performing transmission/reception of ultrasonic signals (See Figures

8A,8B,8C,6(a) and 6 (b)) to/from a subject , analyzing said signals with **(compression)**

and without **(pre-compression)** pressure applied to the subject **(See Paragraphs**

[0017]-[0019]) ; storage means for storing the properties of signals detected with said

ultrasonic probe **(See Paragraphs [0026] and [0034]),** however **Alam et al** does not

teach computing means for calculating the displacement of each measurement point,

and the strain distribution of the tissue of said subject due to said application of

pressure, based upon said correlation coefficient and said phase difference calculated

by said correlation computing means; and display means for displaying said strain

distribution

6.   **Shiina et al** teach Strain ultrasonic system using combined RF and envelope

autocorrelation System wherein computing means for calculating the displacement of

each measurement point, and the strain distribution of the tissue of said subject due to

said application of pressure, based upon said correlation coefficient and said phase difference calculated by said correlation computing means; and display means for displaying said strain distribution and display means for displaying said strain distribution. **(See Fig. 1, Abstract, Theory, Phase Shift, models and methods and pages 1335-1336)** in order to get a precision, accuracy speed measuring of phase domain processing but without the aliasing problem thereby improving the strain signal to noise ratio during strain measurement procedures.

It would have been obvious to one having ordinary skill in the art at the time invention was made to modify an ultrasonic diagnosis system of **Alam et al** to include computing means for calculating the displacement of each measurement point, and the strain distribution of the tissue of said subject due to said application of pressure, based upon said correlation coefficient and said phase difference calculated by said correlation computing means; and display means for displaying said strain distribution and display means for displaying said strain distribution. **(See Fig. 1, Abstract, Theory, Phase Shift, models and methods and pages 1335-1336)** in order to get a precision, accuracy fast (speed) measuring of phase domain processing but without the aliasing problem as taught by **Shiina et al.**

7.   Claims 33-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Alam et al (US Pub. 2002/0040187)** in view of **Shiina et al (Strain imaging using combined RF and envelope autocorrelation)** and **Shiina et al (Tissue Elasticity Reconstruction Base on 3-Dimensional Finite-Element Model).**

8.   **Alam et al** and **Shiina et al** teach the claimed invention see rejection supra,
however **Alam et al** and **Shiina et al** do not teach using two-dimensional or three-
dimensional finite model for computing the elastic modulus strain distribution.

9.   **Shiina et al (Tissue Elasticity Reconstruction Base on 3-Dimensional Finite-
Element Model) teach** Strain ultrasonic System wherein three-dimensional finite model
are created for computing the elastic modulus distribution (See Page 3398) in order to
detect tumors more quantitatively than conventional method on the 2-D model, even for
lesions invisible in a B-mode image.

It would have been obvious to one having ordinary skill in the art at the time
invention was made to modify an ultrasonic diagnosis system of **Alam et al and Shiina
et al** wherein three-dimensional finite model are created for computing the elastic
modulus distribution (See Page 3398) in order to detect tumors more quantitatively than
conventional method on the 2-D model, even for lesions invisible in a B-mode image as
taught by **Shiina et al.** Also, **Shiina et al is capable of creating a** two-dimensional
finite model for computing the elastic modulus strain distribution since the two-
dimensional finite model has to be compared to the three-dimensional finite model for
quantitative verifications.

Allowable Subject Matter

10.   Claims 5-19, 24-32 objected to as being dependent upon a rejected base claim,
but would be allowable if rewritten in independent form including all of the limitations of
the base claim and any intervening claims.

11.   The following is an examiner's statement of reasons for allowance:

    Sarvazyan et al (US Patent 5,524,636) teach a method and Apparatus for Elasticity

imaging wherein an apparatus and method for imaging a portion of the body tissue comprises

support for a portion of the tissue, and a force applying member that tends to deform the tissue

relative to a reference position, while at the same time a pressure pattern distribution is

generated indicating areas of greater pressure which are a function of the amount of

deformation and localized portions of the tissue being deformed.

    Alam et al (US Pub. 2002/0040187) teach method and system of signal processing for

generating estimates of tissue strain wherein frequency shifting of post-compression spectral

data to determine a scaling factor which approximates the applied tissue strain. The scaling

factor can be determined by finding the maximum correlation between the frequency shifted

post-compression data to the pre-compression data and can also be determined by minimizing

the variance of the ratio of such data. Correlation tracking and maximum correlation magnitude

techniques for improving the results of elastography are also presented.

    Radulescu (US Patent 7,223,241) teach method and system for elasticity imaging

wherein setting a region of interest about an ultrasound image; compressing cyclically a

biological tissue; acquiring at least one of a plurality of RF frame data at an imaging-relevant

frame rate; analyzing said at least one of said plurality of RF frame data using a compression

feedback algorithm; displaying a comparison of a quantitative indication of said at least one of

said plurality of RF frame data across at least one displacement to a threshold value across said

at least one displacement; determining an acceptable compression value based upon said

comparison; determining said compression is satisfactory; and displaying an elasticity image of said biological tissue at said imaging-relevant frame rate.

No prior art of records teaches or suggests an ultrasound diagnosis method/system which comprise computing means which detects the position which exhibits the maximum correlation coefficient by varying said measurement points in said ultrasound beam direction at a pitch half the wavelength of said ultrasonic signals, calculate autocorrelation functions for said envelope signals under pressure, and correlation coefficient is calculated between said autocorrelation functions by varying the phase between said autocorrelation functions at a pitch half the wavelength of said ultrasonic signals corresponding to said variation of said measurement points, thereby obtaining the position of each measurement point which exhibits the maximum correlation coefficient between said envelope signals with and without application of pressure.

The computing means set measurement points on frame data of said envelope signals with and without pressure applied to said subject; said frame data serving as slice data being stored in said storage means, and detect the position of each measurement point which exhibits the maximum correlation coefficient between said envelope signals with and without application of pressure by varying a two-dimensional correlation window at least in two-dimensional directions as to said frame data; said two-dimensional correlation window surrounding said measurement points which are to be used for correlation, as well as calculating the phase difference between said RF signals with and without application of pressure; and wherein said computing means

include displacement computing means for calculating at least the two-dimensional

displacement of each measurement point due to said application of pressure based

upon said position of each measurement point which exhibits said maximum

correlation coefficient and said phase difference calculated by said correlation

computing means in combination with the other claimed elements.

Any comments considered necessary by applicant must be submitted no later

than the payment of the issue fee and, to avoid processing delays, should preferably

accompany the issue fee. Such submissions should be clearly labeled "Comments on

Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to LAWRENCE N. LARYEA whose telephone number is

(571)272-9060. The examiner can normally be reached on 9:30 a.m.-5:30 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the

organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the

Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information

system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LNL   /Eric F Winakur/
                                           Primary Examiner, Art Unit 3768